K131661

Innovative Medical Manufacturing Company

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Unified Code:16980249

510(k) Summary of Safety and Effectiveness

1. General Information

Submitted by: Innovative Medical Manufacturing Company
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Date of preparation: 10/14/2013

NOV 0 5 2013

2. Device Information

Common Name: Syringe Kit
Proprietary Name: IMM™ Infusion Syringe Set
Classification Name: Piston Syringe; Intravascular Administration Set
Product code: FMF(880.5860)
FPA (880.5440)

3. Predicate Device

Trade Name	510(k) Number	Decision Date
Vascular Auto-Fill Syringe Kit	K063851	2007/1/26
Multi-Ad Dispensing system	K792227	1979/12/20

4. Device Description

IMM™ Infusion Syringe Set is single use product which contains disposable parts of one spike infusion set for connecting to fluid reservoir and fluid delivery, and a control syringe for delivery fluid supply from a solution bag to access device for purpose of delivering controlled volume of fluids from reservoirs consistent with the labeled route of administration of fluids by manual operation. The distal end of the set is a dual valve with 6% taper design for connecting to other access device such as needles before use. The IMM Infusion Syringe Set is provided sterile in fluid path, and to be disposed after single patient use.

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5. Indication for Use

IMM™ Infusion Syringe Set is intended for delivering controlled volume of fluids from reservoirs consistent with the labeled route of administration of fluids by manual operation.

6. Technological Characteristics

The IMM™ Infusion Syringe Set is single use device, and can be delivered in unit sterile package or in bulk non-sterile shipment for further packaging. It allows easy operation and replacement before use.

7. Substantial equivalence

The IMM™ Infusion Syringe Set has the same indication for use and similar characters with the predicated device. The technological characteristics of the IMM device are as same as the predicate device.

Element of Comparison	Subject Device K131661	Vascular K063851	B. Braun K792227
Intended Use	For delivering controlled volume of fluids from reservoirs of labeled route of administration of fluids by manual operation	Same	Similar
Construction	Spike inlet, PVC tubing, dual check valve, syringe	Similar, except additional extension	Spike inlet, PVC tubing, dual check valve, syringe
Transparency	Tubing of fluid line is transparency	Same	Same
Tubing/fitting bonding strength	Tensile strength >15 N	Similar	Similar
Flow regulator Clamping efficacy	From zero to maximum in gravity use	Same	Same
Syringe	12ml	12ml	10ml
Interface	Luer fitting	Luer fitting	Luer fitting
Material	PP, PVC, PC, ABS	PP, PVC, PC, ABS	Similar
Sterility	Single use	Same	Same
Sterilization method	EtO	EtO	EtO

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8. Performance Summary

The non-clinical functional and performance tests demonstrated that IMM™ Infusion Syringe Kit meets the specific requirements established in voluntary standards: ISO8536-4 and ISO7886-1.

9. Material

The Infusion syringe set is composed of materials that have been tested in accordance with ISO10993 and have been determined to be suitable for the intended use of this product.

10. Safety and Effectiveness

All verification and validation test data indicated that the IMM Infusion syringe set can perform as intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 5,2013

Innovative Medical Manufacturing Company
Ms. Lucy Huang
Regulation Specialist
No.. 107, Lane 181, Sect 1.,
Yong Jane Road
Chunan, MIAOLI
CHINA 350

Re: K131661
Trade/Device Name: IMM™ Infusion Syringe Set
Regulation Number: 21 CFR 880.5860, 21 CFR 880.5840
Regulation Name: Piston Syringe, Intravascular Administration Set
Regulatory Class: II
Product Code: FMF, FPA
Dated: September 13, 2013
Received: September 25, 2013

Dear Ms.Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131661

Device Name: IMM™ Infusion Syringe Set

Indications for Use:

IMM™ Infusion Syringe Set is intended for delivering controlled volume of fluids from reservoirs consistent with the labeled route of administration of fluids by manual operation.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Richard C. Chapman
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